IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

STEPHANIE DENISE BARNETT AND KEVIN CRAWFORD,	)	Civil Action No.:
Plaintiffs,	)	Judge:
v.	)	
BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	**COMPLAINT WITH JURY DEMAND**
Defendant.	)	

Plaintiffs Stephanie Barnett and Kevin Crawford ("Plaintiffs"), by and through the undersigned attorneys, hereby bring this cause of action for personal injuries suffered as a proximate result of Plaintiff Stephanie Barnett being prescribed and using the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system). At all times relevant hereto, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Bayer Healthcare Pharmaceuticals, Inc. ("Bayer").

PARTIES AND CITIZENSHIP

1. At all relevant times hereto, Plaintiffs Stephanie Barnett and Kevin Crawford were residents and citizens of Cleveland, Ohio.

2. Defendant Bayer Healthcare Pharmaceuticals Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West

Belt Road, Wayne, New Jersey 07470. Defendant Bayer Healthcare Pharmaceuticals, Inc., can be served with process through its registered agent for service of process in Ohio, Corporation Service Company, 50 West Broad St., Suite 1800, Columbus, Ohio 43215.

3. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

4. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

5. Defendant Bayer Healthcare Pharmaceuticals Inc. is the holder of the approved New Drug Application (NDA) for contraceptive device Mirena®.

6. Bayer is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive system, Mirena®.

7. Bayer does business in Ohio through the sale of Mirena® and other prescription drugs in the state.

8. At all times relevant, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena®.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs,

and because Defendant is incorporated and has its principal places of business in states other than the state in which the named Plaintiff resides.

10. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs' claims occurred, in part, in the Northern District of Ohio, Eastern Division.

FACTS

12. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

13. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases 20 µg/day of levonorgestrel, a prescription medication used as a contraceptive.

14. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

15. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendants admit "i]t is not known exactly how Mirena works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

16. The Mirena® intrauterine system ("IUS") is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5)

years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

17. The package labeling recommends that Mirena® be used in women who have had at least one child.

18. Mirena®' s label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion.

19. Mirena®'s label also describes perforation as an "uncommon" event, despite the numerous women who have suffered migration and perforation post-insertion, clearly demonstrating this assertion to be false.

20. Defendant has a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

21. In or around December 2009, Defendant was contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central", a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

22. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®' s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

23. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

24. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage is a woman becomes pregnant on Mirena®.

25. Finally, Defendant falsely claimed that Defendant's product required no compliance with a monthly routine.

26. Plaintiff Stephanie Barnett is currently 45 years old.

27. Plaintiff had the Mirena® IUS inserted in 2008, by Lakewood Midwifery in Lakewood, Ohio. While she suffered some mild discomfort and bleeding, the insertion was uncomplicated.

28. On or about September 12, 2012, as the result of vaginal bleeding, Plaintiff underwent a pelvic ultrasound and a transvaginal ultrasound at Lakewood Hospital. The radiologist was unable to visualize the Mirena IUD within Plaintiff's uterus.

29. In October, 2012, Plaintiff received an abdominal x-ray at MetroHealth Medical Center, which demonstrated that the Mirena was outside of her uterus and within her abdomen.

30. Plaintiff is scheduled to undergo a laparoscopy under general anesthesia on November 28, 2012 at MetroHealth Medical Center.

31. This procedure carries with it risks, such as adverse reaction to anesthesia, infection, perforation of other organs, and adhesion formation, to name a few.

FIRST CAUSE OF ACTION
PRODUCT DEFECT IN DESIGN OR FORMULATION
OHIO REVISED CODE § 2307.75

32. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

33. At all times herein mentioned, Defendant manufactured, designed, formulated, produced, created, made, constructed and/or assembled Mirena®, used by Plaintiff.

34. Defendant's Mirena® was defective in that at the time Mirena® left the control of Defendant, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

35. Mirena® was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff.

36. At all times herein mentioned, Mirena® was in a defective condition and unsafe, and Defendant knew, had reason to know, or should have known that said Mirena® was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendant.

37. The nature and magnitude of the risk of harm associated with the design and formulation of Mirena®, including uterine migration and perforation, is high in light of the intended and reasonably foreseeable use of Mirena® as a reversible form of contraceptive.

38. It is highly unlikely that Mirena® users would be aware of the risks associated with Mirena® through either warnings, general knowledge or otherwise. Plaintiff was not aware of said risks.

39. The likelihood was high that the design or formulation would cause the harm of uterine migration and perforation, in light of the intended and reasonably foreseeable use of Mirena® as a reversible form of contraceptive.

40. The design or formulation did not conform to any applicable public or private product standard that was in effect when Mirena® left the control of its manufacturer, the Defendant.

41. The design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonable foreseeable manner as a reversible form of contraceptive. It was more dangerous than Plaintiff expected.

42. The intended or actual utility of Mirena® is not of such benefit to justify the risk of uterine migration, perforation and even infertility.

43. There was both technical and economic feasibility, at the time Mirena® left Defendants' control, of using an alternative design or formulation that would not cause uterine migration or perforation.

44. The defective design or formulation of Mirena® was not caused by an inherent characteristic of the Mirena® which is a generic aspect of all contraceptive medications that cannot be eliminated without substantially compromising Mirena®' usefulness or desirability and which is recognized by the ordinary person. This is demonstrated by numerous safer alternative therapies that are available on the market to prevent contraception, without the harmful side effects that can result from Mirena® use.

45. A practical and technically feasible alternative design or formulation was available that would have prevented the harm for which Plaintiff suffered.

46. By reason of the foregoing, the Defendant is liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in design and formulation.

SECOND CAUSE OF ACTION
PRODUCT DEFECT DUE TO INADEQUATE WARNING AND/OR INSTRUCTION
OHIO REVISED CODE § 2307.76

47. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

48. Defendant had a duty to warn Plaintiff of the risks associated with Mirena®, namely, the risk of spontaneous migration and uterine perforation.

49. Defendants knew, or in the exercise or reasonable care, should have known about the risk of spontaneous migration and uterine perforation.

50. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of spontaneous migration and uterine perforation, in light of the likelihood that their product would cause spontaneous migration and uterine perforation, for which Plaintiff suffered.

51. Defendants' Mirena® is defective due to inadequate post-marketing warning or instruction.

52. Defendants knew, or in the exercise or reasonable care, should have known about the risk that their Mirena® causes spontaneous migration and uterine perforation.

53. Defendants failed to provide post-marketing warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of

spontaneous migration and uterine perforation, in light of the likelihood that the product causes spontaneous migration and uterine perforation, for which Plaintiff suffered.

54. Defendants' product does not contain a warning or instruction regarding spontaneous migration and uterine perforation for normal healthy individuals.

55. The risk of spontaneous migration and uterine perforation is not an open and obvious risk or a risk that is a matter of common knowledge in regards to Mirena®.

56. By reason of the foregoing, the Defendant is liable to the Plaintiff, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective due to inadequate warning or instruction.

THIRD CAUSE OF ACTION
PRODUCT DEFECT IN FAILURE TO CONFORM TO REPRESENTATIONS
OHIO REVISED CODE § 2307.77

57. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

58. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

59. The Defendant's product was defective in that, when it left the control of Defendant, the product did not conform to representations made by Defendant.

60. Said representations are false, misleading, and inaccurate.

61. Defendant describes and represents that their product has characteristics that simply do not conform to reality. Rather than acknowledging that Defendant's product causes spontaneous migration and uterine perforation, Defendants describe Mirena® as being safe.

62. These representations are in stark contrast to the spontaneous migration and uterine perforation that Mirena® does actually cause.

63. While Plaintiff believes and avers that Defendant acted negligently and recklessly in making the representations, in the event Defendant is not found to have acted negligently or recklessly, Defendant is still liable for the damages and injuries suffered by Plaintiff pursuant to ORC § 2307.77.

64. By reason of the foregoing, the Defendant is liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective in that it did not conform, at the time it left the control of Defendant, to representations made by Defendant.

FOURTH CAUSE OF ACTION
PUNATIVE DAMAGES
OHIO REVISED CODE § 2307.80

65. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

66. Plaintiff's injury was the result of misconduct of Defendant that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question.

67. Defendant fraudulently and in violation of applicable regulations of the FDA withheld from the FDA information known to be material and relevant to the harm that the Plaintiff suffered or misrepresented to the FDA information of that type.

68. By reason of the foregoing, the Defendant is liable to the Plaintiff for punitive damages, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a product that is defective under the Ohio Product Liability Act.

FIFTH CAUSE OF ACTION
LOSS OF CONSORTIUM

69. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

70. Plaintiff Kevin Crawford is the husband of Stephanie Barnett.

71. As a result of the medical conditions developed by his wife and the medical treatment and hospitalization that she has and will endure, Plaintiff Kevin Crawford:

a. lost a substantial measure of his wife's household services; and

b. lost, and will continue to lose in the future, a substantial measure of his wife's consortium.

72. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff Kevin Crawford suffered injuries.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

JURY DEMAND

A jury trial is requested.

Dated: November 7, 2012

Respectfully submitted,

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